UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

IN RE: ZETIA (EZETIMIBE) ANTITRUST LITIGATION	MDL No. 2:18-md-2836
THIS DOCUMENT RELATES TO: ALL DIRECT PURCHASER CASES	

BRIEF IN SUPPORT OF DEFENDANTS GLENMARK PHARMACEUTICALS, LTD. AND GLENMARK GENERICS INC., USA'S MOTION TO DISMISS DIRECT PURCHASER PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT

J. Kevin Fee (Bar. No. 88376)
Teri J. Diaz (Bar. No. 87457)
MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Ave., NW
Washington, D.C. 20005
Tel: 202.739.3000
Fax: 202.739.3001
kevin.fee@morganlewis.com
teri.diaz@morganlewis.com

Steven A. Reed (admitted *pro hac vice*)
R. Brendan Fee (admitted *pro hac vice*)
Zachary M. Johns (admitted *pro hac vice*)
Jessica J. Taticchi (admitted *pro hac vice*)
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103
Tel: 215.963.5000
Fax: 215.963.5001
steven.reed@morganlewis.com
brendan.fee@morganlewis.com
zachary.johns@morganlewis.com
jessica.taticchi@morganlewis.com

Stacey Anne Mahoney (admitted *pro hac vice*)
MORGAN, LEWIS & BOCKIUS LLP
101 Park Ave.
New York, NY 10178
Tel: 212.309.6000
Fax: 212.309.6001
stacey.mahoney@morganlewis.com

Counsel for Defendants Glenmark Pharmaceuticals, Ltd. and Glenmark Pharmaceuticals Inc., USA incorrectly identified as Glenmark Generics Inc., USA

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

I. INTRODUCTION

In *FTC v. Actavis*, 570 U.S. 136 (2013), the Supreme Court held that Hatch-Waxman patent settlements that include a large cash payment from a branded drug manufacturer to a generic drug competitor can "sometimes" violate the antitrust laws. *Id.* at 141. Because Hatch-Waxman cases involve a branded drug company suing a generic drug company for alleged patent infringement based upon the anticipated launch of a competing product, settlement payments flowing from the brand plaintiff to the generic defendant have been labeled "reverse" payments. Plaintiffs' theory in these cases is that the so-called reverse payment is consideration for an agreement by the generic drug company to delay its competitive entry, even when, as here, the settlement results in a license permitting the generic to be sold before the brand's patent and regulatory exclusivities would have otherwise permitted.

Under *Actavis*, a settlement is subject to antitrust scrutiny only if the so-called reverse payment is "large and unjustified." The multiple payments in *Actavis*, for example, totaled approximately $300 million in cash. *Actavis*, 570 U.S. at 145. After the Supreme Court's decision, some courts outside this Circuit expanded the types of arrangements that may qualify as "large and unjustified" payments beyond cash payments, like the ones in *Actavis*, to specific types of noncash terms that those courts deemed tantamount to monetary payments. For example, side deals that compensate the generic drug manufacturer for a service or product in an amount that exceeds fair market value, and provisions in which the brand agrees not to compete with the generic by launching an authorized generic ("AG") version of its branded product, have been found by some courts to qualify in some instances as "large and unjustified" reverse payments sufficient to trigger antitrust scrutiny under the rule of reason.

None of those types of arrangements are present in this case. Direct Purchaser Plaintiffs ("DPPs") do not even attempt to allege—nor could they allege—that the settlement agreement at

issue ("Settlement Agreement") involved a large cash payment or a side deal. Rather, the only form of "payment" that DPPs even attempt to plead is a purported agreement by Merck[1] not to launch an AG in competition with Glenmark's product (a so-called "No AG" provision). DPPs assert that that supposed agreement—which they could only infer exists, because DPPs did not have a copy of the Settlement Agreement when they filed their Consolidated Class Action Complaint ("Complaint")—had significant value to Glenmark because it purportedly guaranteed freedom from price competition for a period of time.

But that single and fundamental predicate for invoking the federal antitrust laws in this case, based upon an inference about what the Settlement Agreement ***might*** provide, is refuted by what the Settlement Agreement actually ***did*** provide. Nothing in the Settlement Agreement, attached hereto as Exhibit A,[2] prevented Merck from engaging in price competition with Glenmark's product once launched. As is clear from its unambiguous terms, the Agreement did not prohibit Merck from launching a new competing product pursuant to its NDA, whether an AG under Merck's trade name or an alternatively branded product under some Merck trademark

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[1] Defendant Schering Corporation ("Schering") owned the patent for ezetimibe and was a wholly owned subsidiary of Defendant Schering-Plough Corporation ("Schering-Plough"). Settlement Agreement at 1; Compl. ¶¶ 12-13. Defendant MSP Singapore Co. LLC ("MSP") held the New Drug Application ("NDA") for ezetimibe pursuant to which it manufactured and sold branded Zetia in the United States. Settlement Agreement at 1. MSP was a subsidiary of Defendant Merck & Co. Inc. Compl. ¶ 15. In 2009, Defendant Merck & Co., Inc. acquired Schering-Plough and the combined entity changed its name to Merck & Co., Inc. Compl. ¶ 14. The company originally known as Merck & Co., Inc. adopted the name Merck Sharp & Dohme Corp. Defendants Schering, Schering-Plough, MSP, Merck & Co. Inc., and Merck Sharp & Dohme Corp. are collectively referred to herein as "Merck" unless otherwise specified.

[2] The Court may properly consider the Settlement Agreement on a Rule 12 motion because it is central to DPPs' claims and is referenced throughout the Complaint. *See, e.g.*, *Cooksey v. Futrell*, 721 F.3d 226, 234 (4th Cir. 2013) (stating that court "must also consider 'documents incorporated into the complaint by reference'" on a motion to dismiss (citation omitted)); *New Beckley Mining Corp. v. Int'l Union, United Mine Workers of Am.*, 18 F.3d 1161, 1164 (4th Cir. 1994) (affirming dismissal where court considered document referred to in the complaint).

other than Zetia. The Agreement also did not prevent Merck from competing with Glenmark's generic product by reducing the price of branded Zetia itself. In fact, Merck ***expressly reserved*** the right to engage in all "conventional commercial conduct in competition with" Glenmark's generic ezetimibe product. Settlement Agreement § 7.2(c). While the Settlement Agreement did provide a limited exclusive license to Glenmark with respect to third parties, exclusive licenses are common and do not violate the antitrust laws—and DPPs do not allege otherwise. Indeed, *Actavis* reaffirmed long-standing case law holding that an exclusive license granted by a patentee is allowed under patent law. *Actavis*, 570 U.S. at 150.

These facts—which the Court can consider on a Rule 12 motion—are fatal to DPPs' claim that Merck made a "large and unjustified" payment to Glenmark, and preclude as a matter of law DPPs' attempts to invoke *Actavis*. That is so because (i) DPPs' allegations about the existence of a commitment by Merck not to launch an AG (which is the only form of payment they assert) are contradicted by the Settlement Agreement, and (ii) their related allegations attempting to ascribe a specific value to that nonexistent agreement lack a reliable foundation and thus fail *Twombly*'s plausibility requirement. Accordingly, DPPs' Sherman Act Section 1 claim, Count I of the Complaint, should be dismissed with prejudice for these reasons alone.

DPPs' Section 1 claim also fails for the independent reason that there are no plausible allegations of anticompetitive effects flowing from the Settlement Agreement. DPPs theorize that, absent the settlement between Glenmark and Merck ("Settlement"), Glenmark would have successfully invalidated Merck's patent and proceeded to launch its generic version of Zetia shortly thereafter. But this is implausible on its face because, as the Complaint acknowledges, Merck prevailed in patent litigation against Mylan on a reissued version of the same patent Glenmark challenged; DPPs' theory of anticompetitive harm requires the opposite resolution of

that issue. Furthermore, Merck's win, which came after a bench trial before the same district court judge who presided over the Merck-Glenmark litigation, was affirmed on appeal by the Federal Circuit. These facts render wholly implausible DPPs' conclusory assertion that Glenmark would have prevailed in its patent litigation against Merck in the absence of the settlement. Without plausible allegations that generic market entry would have occurred before patent expiry absent the settlement, DPPs have not alleged the requisite anticompetitive effects needed to support their Section 1 claim under the rule of reason.

Finally, DPPs' Section 2 conspiracy to monopolize claim fails for the same reasons its Section 1 claim fails, and for the independent reason that they have not pled the essential element of specific intent. Missing from the Complaint are any facts to plausibly suggest that Glenmark acted with the specific intent that Merck achieve a monopoly in the alleged market, or that Merck acted with the specific intent that Glenmark achieve a monopoly. This failure dooms DPPs' Section 2 claim, and thus Count II of the Complaint should be dismissed as well.

II. DPPS' ALLEGATIONS

A. The Hatch-Waxman Regulatory Scheme.

The Hatch-Waxman amendments to the Food Drug and Cosmetic Act were designed to provide an expedited regulatory pathway to the market for generic drug products that are bioequivalent to the brand drug. Compl. ¶ 28. Generic drug suppliers wishing to take advantage of that expedited path to market must file an Abbreviated New Drug Application ("ANDA"), which relies on the findings of safety and effectiveness included in the brand manufacturer's original New Drug Application ("NDA") and requires the ANDA applicant to show bioequivalence. *Id.* In connection with its ANDA, a generic supplier wishing to market a generic copy of a branded product must provide the FDA and the NDA holder with a certification that the generic medication will not infringe any valid and enforceable patents listed

in the FDA's Orange Book. *Id.* ¶ 36. One such certification is a Paragraph IV certification by the generic that the patent for the brand drug is invalid, unenforceable, or will not be infringed by the product described in the ANDA. *Id.* Upon receiving a Paragraph IV certification, the branded firm may file a patent infringement suit immediately and is not required to wait until the generic product is launched in order to assert infringement. *Id* ¶ 37. If the patent holder files such a suit within 45 days of receipt of the generic's certification, FDA approval of the ANDA will be stayed until the earlier of 30 months or the issuance of a court decision that that patent is invalid or not infringed by the ANDA product. *Id.*

To encourage development of generic medications, the generic drug manufacturer that is the first to file a substantially complete ANDA containing a Paragraph IV certification is awarded a 180-day exclusivity period to market the generic version of the drug, during which the FDA cannot grant final approval to any other ANDA. *Id.* ¶ 39. That first-to-file exclusivity does not apply to an AG, which is a generic product that is made available for sale using the brand company's already-approved NDA and can be launched either by the brand company itself or through a license to another company. *Id.* ¶ 40. While the launch of an AG is one way in which branded companies may compete with a generic, it is not the only way that they compete. Nor does the Complaint allege that branded companies in general, or Merck specifically, always or even routinely launch an AG in response to generic entry. Rather, DPPs merely assert that brand companies "can" and "often" do launch AGs as one way in which they could competitively respond to generic entry, *id.* ¶¶ 40, 55, and cite examples where Merck has done so in the past with respect to different products not at issue in this case, *id.* ¶ 185.

B. <u>The '721 Patent Litigation Between Merck and Glenmark.</u>

In the early 1990s, Merck invented a chemical compound called ezetimibe. *Id.* ¶ 1. Ezetimibe belongs to a broad class of medications that are used to reduce cholesterol levels. *Id.*

¶¶ 96-97. Merck ultimately secured a series of patents related to ezetimibe, with the primary patent at issue in DPPs' Complaint at U.S. Patent No. RE 37,721 (the "'721 patent")—a compound patent. *Id.* ¶ 1. On December 27, 2001, Merck submitted NDA (NDA No. 21-445) to the FDA seeking approval to market a cholesterol-lowering medication that contained ezetimibe as the active pharmaceutical ingredient under the trademark Zetia. *Id.* ¶ 131. On October 25, 2002, the FDA approved Merck's NDA and Merck launched Zetia shortly thereafter. *Id.* ¶ 135.

On October 25, 2006, Glenmark filed an ANDA (ANDA No. 78-560) seeking FDA approval to market a generic version of Zetia (NDA No. 21-445), along with a Paragraph IV certification that the '721 patent was invalid, unenforceable, and not infringed. *Id.* ¶¶ 146, 148. As required under the Hatch-Waxman Act, on February 9, 2007, Glenmark notified Merck of its ANDA filing. *Id.* ¶ 149. On March 22, 2007, Merck sued Glenmark for infringement of the '721 patent in the District of New Jersey. *Id.* ¶ 150. Following extensive litigation, the case was set for trial on Glenmark's invalidity challenge to the '721 patent—an issue as to which Glenmark bore the burden of proof. *Id.* at ¶¶ 171, 176. With two days to spare before trial, the parties reached a settlement of the patent litigation. *Id.* ¶ 179. As part of that settlement, Merck agreed to grant Glenmark a limited license under the '721 patent that cleared the way for Glenmark to sell its generic version of Zetia before it otherwise would have if Merck had prevailed in the patent litigation. Settlement Agreement § 5.3.

C. Related Patent Litigation Involving Other ANDA Filers.

While the Merck-Glenmark litigation over the '721 patent was pending, Mylan filed the second ANDA for generic Zetia in April 2010. Compl. ¶ 221. Mylan's ANDA included a Paragraph IV certification that its generic Zetia would not infringe Merck's '721 patent, triggering Merck's filing of a patent infringement suit against Mylan in June 2010. *Id.* ¶¶ 222-23. That patent infringement litigation proceeded to a bench trial in December 2011 before the

Honorable Jose Linares in the District of New Jersey, who had also presided over the Merck-Glenmark '721 patent invalidity litigation. *Id*. ¶¶ 176-177, 229, 240. On April 27, 2012, Judge Linares upheld the validity of Merck's patent—which by that point the '721 patent had been reissued as the RE 42,461 patent (the "'461 patent")—holding that the '461 patent was valid and enforceable and that Mylan's allegations of inequitable conduct by Merck were "without merit." *Id*. ¶¶ 229-30, 241; *Schering Corp., et al. v. Mylan Pharms., Inc.*, No. 09-cv-6383, ECF No. 444, at 1 (D.N.J. Apr. 27, 2012). On February 7, 2013, the Federal Circuit affirmed in full Judge Linares' findings. Compl. ¶ 241 n.62; *Merck Sharp & Dohme Corp. et al. v. Mylan Pharms. Inc.*, No. 2012-1434, ECF No. 49-1 (Fed. Cir. Feb. 7, 2013).

In July 2010, Teva filed the third ANDA for generic Zetia, prompting Merck to sue Teva. Compl. ¶¶ 225-26. In July 2011, before Merck began its separate trial with Mylan, Merck and Teva settled their litigation. *Id*. ¶¶ 231, 240. As part of the Merck-Teva settlement, Teva admitted that the '461 patent was "valid and would be infringed by" Teva's generic. *Id*. ¶ 231. After Merck prevailed at trial against Mylan on its patent claims but before the Federal Circuit affirmed, Sandoz filed the fourth ANDA, prompting Merck to sue Sandoz. *Id*. ¶¶ 243-44. In response, Sandoz claimed that its manufacture of generic Zetia would not infringe Merck's '461 patent. *Id*. ¶ 245. In September 2013, Merck and Sandoz settled, with Sandoz admitting as part of the settlement that Merck's '461 patent was "valid and would be infringed by" Sandoz's generic. *Id*. ¶ 247.

D. Overview of DPPs' Antitrust Claims.

DPPs allege that in resolving the infringement litigation relating to the '721 patent, Merck and Glenmark agreed to an unlawful reverse payment settlement. *Id*. ¶ 183. Because they did not have a copy of the Settlement Agreement before filing suit, DPPs could only guess about its contents. *Id*. ¶ 182. In the Complaint, DPPs speculate (incorrectly) that Merck "paid"

Glenmark to "stay out of the market for almost five years" by agreeing not to launch an AG in competition with Glenmark's product. *Id.* ¶ 3. In an attempt to fit this case into the *Actavis* paradigm, DPPs purport to assign a value to that nonexistent commitment by estimating the revenue they believe is attributable to "additional sales" that Glenmark made following the launch of its product in 2016 over what DPPs contend Glenmark would have realized if it had launched its product in December 2011 and Merck had launched an AG. *Id.* ¶¶ 212-17. DPPs' calculation is premised on a number of inaccurate assumptions, including that: (i) Merck agreed to refrain from competing against Glenmark's generic by launching its own AG with a Merck trade name or another alternative product under a different Merck trademark; (ii) Merck agreed not to engage in price competition with Glenmark's generic product by, for example, reducing its price for branded Zetia; and (iii) Glenmark would have prevailed in challenging the '721 patent and received FDA approval and launched its product, all by December 2011.

In support of the last assumption—that, but for the settlement, Glenmark would have won the underlying patent case and launched its product sooner—DPPs cite to statistics regarding the success rates in patent cases generally. *Id.* ¶ 51. But DPPs do not explain the relevance of these generalized statistics here, given that (i) the patent at issue in the Merck-Glenmark litigation was a complex compound patent; (ii) the issue to be tried was invalidity, as to which Glenmark had the burden of proof by clear and convincing evidence; and (iii) Judge Linares later found the patent to be valid following a bench trial in a decision that was affirmed by the Federal Circuit. *See id.* ¶¶ 100, 134. Indeed, DPPs do not point to a ***single*** compound patent that had successfully been challenged in the context of Hatch-Waxman litigation at the time of the Settlement, and cannot cite to any case in which the '721 patent was successfully challenged on any ground.

Nevertheless, DPPs claim that, as a result of the hypothetical No-AG covenant, Merck improperly maintained a monopoly for sales of Zetia until December 12, 2016, when Glenmark launched its generic version pursuant to the license obtained in the Settlement. *Id.* ¶ 317. DPPs bring two claims against Merck and Glenmark. The first claim is for alleged violation of Section 1 of the Sherman Act based on an alleged "unlawful reverse payment" agreement. *Id.* ¶ 315. The second claim is for violation of Section 2 of the Sherman Act based on an alleged conspiracy to monopolize a purported market for Zetia and its generic counterparts. *Id.* ¶¶ 324-26.[3]

E. The Terms of the Merck-Glenmark Settlement Agreement.

The Settlement Agreement—which forms the basis for DPPs' claims—contains recitals setting forth that Schering owned the '721 patent, MSP held the NDA for Zetia pursuant to which MSP marketed and sold branded Zetia, and Schering granted "MSP an exclusive license under the '721 patent to make, have made, use and sell ezetimibe in the United States." Settlement Agreement at 1. In resolving the litigation of the '721 patent, Schering granted a license to Glenmark for the sale of generic ezetimibe sold pursuant to Glenmark's ANDA in the United States beginning no later than December 12, 2016. *Id.* at Art. 4 & 5.[4] This allowed

[3] DPPs' unreasonably narrow market definition, which fails to account for many other products with which Zetia and Glenmark's generic product compete, is defective as a matter of law. *See Mylan Pharms Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 436-38 (3d Cir. 2016). However, solely for purposes of argument, Glenmark does not challenge DPPs' market definition in the instant Motion.

[4] December 12, 2016 overlapped with Merck's period of pediatric exclusivity for Zetia. Settlement Agreement § 5.3. The FDA may award six months of exclusivity beyond expiration of a patent provided a NDA sponsor undertakes certain pediatric studies. *See* 21 U.S.C. § 355a; *see also AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1341 (Fed. Cir. 2015).

Glenmark to launch its generic sooner than it would have had it lost the patent litigation (as Mylan subsequently did). *Id.*

The license provided to Glenmark was exclusive to Glenmark and its affiliates "with respect to the commercial distribution and sale of ***Generic Ezetimibe***." *Id.* § 5.3 (emphasis added). "Generic Ezetimibe" is defined in the Settlement Agreement to include two categories of products that contained ezetimibe as the sole active ingredient. *Id.* § 1.14. The first category consisted of ezetimibe products sold pursuant to an approved ANDA or Section 335(b)(2) application.[5] *Id.* § 1.14(a). The second category consisted of ezetimibe products sold pursuant to Merck's NDA. *Id.* § 1.14(b). The latter category was subject to important exceptions. First, it did not include products sold pursuant to Merck's NDA "under the trademark Zetia." *Id.* In other words, the limited license granted to Glenmark did not prevent Merck from continuing to sell its branded product. Second, it did not include products sold pursuant to Merck's NDA under "another trademark [other than Zetia] or trade name of Schering, MSP or their Affiliates." *Id.*[6] Thus, while the license granted to Glenmark may have limited Merck's ability to license its patent to another third party to launch an AG, it did not prevent Merck from selling an AG itself under a Merck trade name, or from selling another branded product under its NDA using a new Merck trademark.

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[5] In addition to an ANDA, an applicant may file an application under 21 U.S.C. § 355(b)(2), which would allow the applicant to obtain approval if it can satisfy the same requirements of a stand-alone NDA, but to do so the applicant may rely, in part, on clinical safety and effectiveness studies not conducted or owned by the applicant, including previous FDA findings that an approved branded drug is safe and effective.

[6] The definition of "Generic Ezetimibe" reads: "The term 'Generic Ezetimibe' shall mean a drug product containing ezetimibe as its sole active ingredient (a) that refers to the Approved Zetia Product as the reference-listed drug in an ANDA or pursuant to an application under 21 USC § 355(b)(2) or (b) that is sold pursuant to NDA No. 21-445 but is not sold under the trademark Zetia or another trademark or trade name of Schering, MSP, or their Affiliates." Settlement Agreement § 1.14.

Further, while the license in Section 5.3 was "exclusive," it plainly was not the sole license to the patent, as the use of the defined term "Generic Ezetimibe" makes clear. Schering did not agree to restrict its own or MSP's use of the patent in connection with the sale of Zetia, any other trademarked version of ezetimibe, or any unbranded product (*i.e.*, authorized generic) sold under a Merck trade name of Schering or one of its affiliates. *Id.* §§ 1.14, 5.3. Instead, the license prevented Merck from licensing third parties to sell Generic Ezetimibe during the exclusivity period. *Id.* And even as to that limited exclusivity, Merck expressly retained the right to license the '721 patent to other third party ANDA holders, but agreed that such a grant would have the effect of accelerating Glenmark's license. *Id.* § 5.3 (noting that Glenmark's license was "subject only to Schering's right to grant rights to or otherwise authorize Third Parties to make, have made, use, sell, offer to sell, import, or distribute Generic Ezetimibe pursuant to such Third Parties' ANDAs.…"); *id.* § 5.4(c) (providing that Glenmark's Entry Date would be accelerated if a third party ANDA holder received an earlier license date for Generic Ezetimibe or Generic Vytorin[7]).

The parties' respective covenants—*i.e.*, what they specifically committed to do and refrain from doing—are found in Article 7 of the Settlement Agreement. There is no covenant by Merck not to launch an AG or otherwise refrain from competing with Glenmark's generic. *See id.* § 7.2. To the contrary, Merck expressly retained the ability to engage in "conventional commercial conduct in competition with" Glenmark, with no limitations. *Id.* § 7.2(c).

The only payment by Merck to Glenmark in the Settlement Agreement is found in Section 7.3, which provided for the reimbursement of documented attorneys' fees, costs, and

[7] Vytorin is another Merck cholesterol control medication, which contains ezetimibe and simvastatin as active ingredients. *See* Compl. ¶ 223 n.58.

expenses related to the prosecution of the patent action, up to a specified cap. *Id*. § 7.3. There are no other payments referenced in the Settlement Agreement, nor are any alleged in the Complaint. *See id.* § 10.10 (noting that the Settlement Agreement represents "the entire understanding and agreement of the Parties with regard to the matters addressed herein.").

III. LEGAL STANDARD

To withstand a Rule 12(b)(6) motion, a complaint alleging a Sherman Act violation "must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). A plaintiff must, therefore, do more than "plead facts that are merely consistent with a defendant's liability"; the facts alleged must "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. at 678 (citations omitted). When the allegations of a pleading fail to plausibly suggest any entitlement to relief, "this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558. This will prevent the "potentially enormous expense of discovery" in an antitrust case such as this that lacks any plausible basis. *Id*. at 559.

IV. ARGUMENT

A. DPPs' Section 1 Sherman Act Claim Fails the *Actavis* Test.

To plead a Section 1 claim under the rule of reason, a plaintiff must allege facts to establish the existence of a conspiracy that "produced adverse, anticompetitive effects within the relevant product and geographic market." *Lansdowne on the Potomac Homeowners Ass'n, Inc. v. OpenBand at Lansdowne LLC*, No. 11-cv-872, 2011 WL 5872885, at *3 (E.D. Va. Nov. 22, 2011). Patent settlement agreements like the one at issue here are not "presumptively unlawful" and thus, are evaluated under the rule of reason. *Actavis*, 570 U.S. at 159-60. Under the framework set forth in *Actavis*, only after a plaintiff adequately pleads the existence of a "large

and unjustified payment" is a rule of reason analysis triggered. *Id*. at 158. Then, just like in any other rule of reason Section 1 case, the plaintiff has the burden of defining the relevant market and establishing that the challenged agreement had anticompetitive effects. *Lansdowne on the Potomac Homeowners Ass'n, Inc.*, 2011 WL 5872885, at *3.

Here, DPPs have not pled facts either to establish, as a threshold matter, that the Settlement Agreement included a large and unjustified payment or to plausibly demonstrate that Glenmark would have won the patent litigation such that the Settlement Agreement had actionable anticompetitive effects. As a result, their Section 1 claim fails as a matter of law.

1. *Actavis* Requires an Antitrust Plaintiff to Allege a "Large and Unjustified" Payment Before the Rule of Reason Applies.

The Supreme Court in *Actavis* did not hold that all patent settlement agreements involving any sort of "payment" merit antitrust scrutiny. Rather, *Actavis* held that a patent-settlement agreement must be evaluated under the rule of reason ***if*** a plaintiff has established the existence of a "large and unjustified" reverse payment. 570 U.S. at 158; *see also id.* at 141, 159 (declining to hold so-called reverse payment settlement agreements presumptively unlawful and noting that reverse payment settlements "can sometimes" violate the antitrust laws). *Actavis*, for example, involved allegedly unexplained cash payments amounting to approximately $300 million from the patent holder to three potential generic competitors. *Id*. at 145. The Supreme Court reasoned that such a large reverse cash payment from a brand to generics could be unjustified in light of plaintiff's allegations, and thus, was not immune from antitrust scrutiny. *Id*. at 153-58. As subsequent decisions have explained, under *Actavis*, the question of whether the consideration to the generic entrant is large and unjustified "is central to the antitrust query." *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 551 (1st Cir. 2016).

Some courts outside this Circuit have expanded the term "payment" in *Actavis* to include noncash terms in patent settlement agreements that are tantamount to a cash payment. Side deals benefitting generic companies that exceed fair market value for products or services have been interpreted by some courts to be large and unjustified payments. *See, e.g., King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 409 (E.D. Pa. 2015) (noting that co-development and favorable supply agreements could be considered in answering the question of whether there was a large and unjustified payment). Other courts outside of this Circuit have extended *Actavis* even further, finding that No-AG provisions may in certain circumstances amount to a large transfer of value from the brand to the generic, even though there is in fact no payment by the brand to the generic at all. *See, e.g., King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (hereinafter, *Lamictal*); *see also* Compl. ¶ 84 n.33.[8]

The rationale adopted by some courts outside of the Fourth Circuit for finding that a No-AG provision may be tantamount to a large and unjustified payment is that a branded manufacturer's agreement not to launch an AG—thus effectively guaranteeing the new entrant that it will be the only available generic during the 180-day exclusivity period granted to first-filed ANDA holders under the Hatch-Waxman Act—allows the first-filed ANDA holder to charge more for its product than if it were to compete with another low price alternative. *See Lamictal*, 791 F.3d 394 (explaining that No-AG commitment was designed to "eliminate the risk

[8] In *Actavis*, the payment was obvious. *Actavis*, 570 U.S. at 145. In cases involving side deals, there is also a clear payment by the brand to the generic, but the analysis is more nuanced because the court (and ultimately the trier of fact) must determine whether the payment was for value received under the side deal (*e.g.*, did a payment pursuant to a distribution agreement represent fair market value for the services the brand received) or was the side deal a pretext for making illegitimate payments dressed up under a commercial cover. By contrast, in the case of a so-called No-AG agreement, there is in fact no payment by the brand to the generic at all, but only a purported commitment not to engage in one form of price competition with the generic during its statutorily-mandated 180-day exclusivity period by not launching an AG.

of competition" to the generic upon its launch). The value of that commitment, the argument goes, is sufficient to convince the generic to accept a later entry date in a settlement than it would have accepted absent that commitment. As explained above and at greater length below, Merck made no such commitment here. But even if it did, the notion that Merck or any other patent holder could be deemed to violate the antitrust laws by granting exclusive rights under their patents is directly at odds with the Patent Act, which expressly authorizes exclusive licenses. 35 U.S.C § 261 (providing that a patent holder "may . . . grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States").

Exclusive licenses are routinely granted by patent holders, and the result of such a license is ***increased*** competition, not less. Here, as a result of the Settlement, Glenmark was permitted under the license to launch its generic earlier than it otherwise would have been absent the license. Glenmark did receive limited exclusivity vis-à-vis third parties. But the Court in *Actavis* never intended to subject such "commonplace" and "familiar" settlement forms to antitrust scrutiny, including consideration—such as the grant of an exclusive license—that is expressly authorized by the Patent Act. *Actavis*, 570 U.S. at 151; *see also* Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, 15 MINN.J.L. SCI. & TECH. 3, 29 (2014) (observing "[o]ne theme that Justice Breyer's majority opinion repeated is that extra antitrust deference is due to patent practices challenged under the Sherman Act when the practice is either expressly authorized by the Patent Act or is there 'by fair implication'").

Even under the nonbinding cases that have extended *Actavis* to reach No-AG clauses, a complaint must allege more than a plaintiff's suspicion as to the existence of a No-AG agreement based upon the observation that the brand company opted not to launch an AG. Rather, a plaintiff must allege sufficient factual content to plausibly establish an estimate of the

total value conveyed to the generic by the supposedly anticompetitive No-AG agreement (as opposed to a unilateral business strategy by the brand company). *See In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d at 552 (explaining that plaintiffs "must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment"). If a plaintiff cannot establish the existence of a "large and unjustified reverse payment" with factual allegations suggesting a plausible calculation of the value of the consideration, "their antitrust claims fail, and the [c]ourt need not go any further." *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 716 (N.D. Ill. 2016).

2. DPPs Have Failed to Plausibly Allege a "Large and Unjustified" Payment.

DPPs have not pled the threshold requirement of a "large and unjustified" payment in this case. DPPs infer the supposed commitment not to launch an AG based upon the alleged fact that Merck did not launch an AG as to Zetia. Compl. ¶ 251. But that is not what the Settlement Agreement provides. There is no express prohibition on Merck launching an AG, and the license Glenmark received was only exclusive as to Generic Ezetimibe—a defined term that expressly excluded branded Zetia or other ezetimibe products sold pursuant to Merck's NDA, so long as they were sold under a trademark or trade name of Merck or one of its affiliates. Thus, DPPs' conclusory allegations based upon surmise that Merck agreed not to launch an AG cannot be credited. *Veney v. Wyche*, 293 F.3d 726, 730 (4th Cir. 2002) (stating that courts are not required to "'accept as true allegations that contradict matters properly subject to judicial notice or by exhibit.'" (citations omitted)); *Sopkin v. Mendelson*, No. 17-1626, 2018 WL 3524593, at *2 (4th Cir. July 23, 2018) (refusing to credit allegation in a complaint that was contradicted by document subject to judicial notice); *Murphy v. Capella Educ. Co.*, 589 F. App'x 646, 655 (4th Cir. 2014) (affirming dismissal where complaint's allegations of false statement were "belied by

the attached exhibits"); *see also Burgis v. Dep't of Sanitation City of N.Y.*, No. 13-cv-1011, 2014 WL 1303447, at *4 (S.D.N.Y. Mar. 31, 2014), *aff'd sub nom.*, 798 F.3d 63 (2d Cir. 2015) ("When documents relied upon in the complaint contradict allegations made in the complaint, the court cannot accept as true the contradictory allegations in deciding a motion to dismiss—the court must rely on the documents."). Instead, the Settlement Agreement controls.

a. The Settlement Agreement Does Not Prevent Merck From Competing Against Glenmark With an AG Under Merck's Trade Name, Branded Zetia, or a New Branded Generic.

As discussed, the Settlement Agreement here expressly preserved Merck's ability to compete with Glenmark's product in multiple ways. Among other means, Merck remained free to launch an ezetimibe product pursuant to its NDA that did not carry the Zetia trademark—*i.e.*, an AG—so long as it was sold under Merck's or one of its affiliates' trade name. Settlement Agreement § 1.14(b).[9] In addition to retaining the right to launch its own AG, Merck also retained the right to launch an ezetimibe product pursuant to its NDA using a new trademark, commonly referred to as a branded generic. *See, e.g.*, *Teva Pharm., Indus., Ltd. v. Food & Drug Admin.*, 355 F. Supp. 2d 111, 117 (D.D.C. 2004), *aff'd sub nom.*, *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005) (noting that NDA holders under Hatch-Waxman are free to enter "the market with a brand generic drug during the [180-day] exclusivity period").

The reservation of these forms of competition by Merck reveal that the Complaint lacks any factual support for DPPs' central theory of liability, *i.e.*, that Merck made a "large and unjustified" payment to Glenmark that eliminated the risk of competition.

[9] The term "trade name" in Section 1.14(b) refers to "the name under which a business operates." BLACK'S LAW DICTIONARY (10th ed. 2014) (defining "tradename"); *see also* 15 U.S.C. § 1127 (defining "trade name" under the Lanham Act to mean "any name used by a person to identify his or her business or vocation.").

b. The Limited Exclusive License to Glenmark Did Not Limit Merck's Rights to Practice Its Patent and Did Not Guarantee Glenmark Freedom From Competition.

As the Agreement makes plain, Merck agreed to grant Glenmark a limited exclusive license—something that is both common and entirely legal. Settlement Agreement § 5.3; *see also* 35 U.S.C. § 261. It is beyond dispute that licenses that allow for early entry can be procompetitive because they allow for a generic medication to be sold before the expiration of the brand manufacturer's exclusivity. *Actavis*, 570 U.S. at 154 (noting that a "settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit"). Moreover, it is evident from the face of the Settlement Agreement that the consideration for the limited exclusive license was Glenmark's agreement to settle the litigation. Settlement Agreement §§ 4.1, 4.2. The mere fact that the parties agreed to a limited exclusive license is unremarkable and commonplace in patent settlements, and does not make the license a reverse payment much less one that is "large and unjustified." Indeed, no court has held that the grant of a limited exclusive license is itself a reverse payment or unjustified, particularly in the context where the party receiving that license was the first company to file an ANDA and the first company to engage in protracted litigation challenging the patent.

Even assuming, however, that a limited exclusive license could under certain circumstances constitute a "reverse payment," DPPs still have not pled a large and unjustified payment here. As discussed above, Merck did not covenant to refrain from launching its own AG, and instead retained the right to launch a competing product under its NDA. *Id.* § 1.14(b). Merck also (i) expressly preserved its ability to engage in "conventional commercial conduct in competition with the Glenmark Product," *id.* § 7.2(c); (ii) did not agree to refrain from engaging in price competition with Glenmark by, for example, reducing the price of its branded Zetia

product, *see id.* at Art. 7; and (iii) even retained the right to license the '721 patent to other generic drug manufacturers in connection with their own ANDA versions of Zetia, *id.* § 5.3.[10] Consequently, DPPs' allegations, which are contradicted by the actual terms of the Settlement Agreement, cannot meet the requirement of *Actavis* that there be a reverse payment and that it was "large and unjustified."

The fact that the license to Glenmark was "exclusive" certainly does not support DPPs' theory. First, it was only exclusive with respect to "Generic Ezetimibe" which, as discussed, was a narrowly-defined term. Second, as a matter of law and logic, the license was not the "sole" license under Merck's patent (if it were, Merck could not have continued to sell Zetia). Rather, Glenmark's license remained subject to Schering's prior exclusive licenses granted to MSP. In the patent context, "the word 'exclusive' is not controlling; what matters is the substance of the arrangement." *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998). Here, Schering previously granted MSP a broad "exclusive" license under the '721 patent "to make, have made, use and sell ezetimibe in and for the United States." Settlement Agreement at 1. In examining the scope of the exclusivity Merck later provided to Glenmark, the test "is *not* whether the license is exclusive *as against the licensor*, but rather whether the licensor has promised explicitly or implicitly not to grant any additional licenses to third parties." *Amgen, Inc. v. Chugai Pharm. Co.*, 808 F. Supp. 894, 900 (D. Mass. 1992), *aff'd sub nom., Ortho*

[10] Nor did Merck agree to any of the types of provisions that other courts have found may constitute large payments under *Actavis*, *i.e.*, there is no payment of cash or a favorable side deal. *See* Settlement Agreement. Although the Settlement Agreement allows for the payment of Glenmark's documented attorneys' fees up to a specified cap, Settlement Agreement § 7.3, payment for litigation costs are a "*de facto* safe harbor" under *Actavis*. *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015); *see also Actavis*, 570 U.S. at 156 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement.").

Pharm. Corp. v. Genetics Inst., Inc., 52 F.3d 1026 (Fed. Cir. 1995). Put differently, "obtaining an exclusive license subject to certain defined preexisting uses is comparable to purchasing real estate subject to an easement. The new owner knowingly acquires the property subject to certain reserved rights, but has the exclusive right going forward to exclude anyone else from using the property in the exclusive field of use." *Sigma-Aldrich, Inc. v. Open Biosystems, Inc.*, No. 06-cv-754, 2007 WL 1993439, at *8 (E.D. Mo. July 3, 2007).

Thus, the limited exclusive license granted to Glenmark pursuant to the Settlement Agreement did not, as a matter of law, preclude Schering, the licensor, or MSP, the first exclusive licensee, from launching an AG themselves or otherwise practicing the '721 patent. Settlement Agreement §§ 1.14, 5.3, 7.2(c). Indeed, in the absence of express language indicating that a licensor has given up a particular right, the licensor retains that right. *See Armstrong Pump, Inc. v. Hartman*, 745 F. Supp. 2d 227, 234 (W.D.N.Y. 2010) ("Any right not specifically granted by the licensor remains with the licensor." (quoting *Cook Inc. v. Boston Sci. Corp.*, 208 F. Supp. 2d 874, 879 (N.D. Ill. 2002)); *see also* Settlement Agreement § 10.13 (noting that except for rights "specifically granted pursuant to this Settlement Agreement, no other rights, agreements or covenants are granted or implied by this Settlement Agreement").

DPPs' conjecture that the Settlement Agreement contained a commitment by Merck not to launch a competing product or otherwise engage in price competition with Glenmark's product is also refuted by the other terms of the Settlement Agreement. Article 7 of the Settlement Agreement contains the parties' respective covenants, setting forth what they agreed to do or refrain from doing. Notably absent from Article 7 is any commitment by Merck not to launch an AG. To the contrary, the parties expressly acknowledged that Merck retained the right to engage in "conventional commercial conduct in competition with the Glenmark Product." *Id.*

§ 7.2(c). As DPPs' own allegations make clear, "conventional commercial conduct" in this industry includes the potential launch of an AG. *See* Compl. ¶ 4.

Moreover, as DPPs allege, "[b]ecause generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or between generic versions, is price." *Id*. ¶ 50. To the extent a No-AG commitment has any value to a generic drug manufacturer, it is because it gives the generic drug manufacturer protection against price competition. Here, however, the parties expressly agreed that Merck was free to compete with Glenmark, which competition necessarily includes price competition. Settlement Agreement § 7.2(c). The Complaint is conspicuously silent as to the prices that Merck charged DPPs for branded Zetia following Glenmark's launch of its generic, even though, as direct purchasers of Merck's product, DPPs presumably know what they paid. But, regardless of whether Merck in fact elected to compete by lowering the price of branded Zetia, the express terms of the Settlement Agreement make clear that Glenmark did not extract a promise from Merck that would "eliminate the ***risk*** of competition" on the basis of price by Merck. *See Lamictal*, 791 F.3d at 394 (emphasis added). As such, there is no plausible basis for DPPs to assert that Glenmark received any "large and unjustified" payment within the meaning of *Actavis*. And, DPPs certainly have not plead facts sufficient to provide a reliable foundation for the Court to value Merck's commitments to Glenmark under the actual terms of the Settlement Agreement, much less enough facts to enable this Court to conclude that any "payment" was "large." *See In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d at 552.

c. Merck Retained the Ability to Grant Licenses to Other ANDA Holders.

The Settlement Agreement also makes clear that Merck not only retained the ability to launch an AG under its trade name, a branded generic, and to compete on price, but Merck also

expressly preserved its ability to license to other third-party ANDA holders. Settlement Agreement § 5.3. If Merck licensed the '721 patent to other ANDA holders and allowed an earlier entry date than what was provided to Glenmark, Glenmark's entry would have been accelerated to the earlier date. *Id.* § 5.4(c). Acceleration clauses are generally procompetitive because they lead to an "increase [in] competition in the event that other generics enter[] the market earlier than contemplated by the agreement." *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244, 2015 WL 5610752, at *15 (S.D.N.Y. Sept. 22, 2015), *aff'd in part, rev'd on other grounds*, 848 F.3d 89 (2d Cir. 2017).

d. The Settlement Agreement Here Is Significantly Different Than the Agreements at Issue in the Other Cases DPPs Cite.

The above-described provisions of the Settlement Agreement are significantly different than the terms that were at issue in the cases DPPs cite in their Complaint, Compl. ¶ 84 n.33, where courts in other Circuits applied *Actavis* to express agreements not to launch an AG. For example, *Lamictal* involved allegations that GlaxoSmithKline, the brand manufacturer of Lamictal, expressly promised Teva not to market an AG until after Teva's 180-day exclusivity expired. 791 F.3d at 397. The Third Circuit concluded that allegations of an express No-AG clause, coupled with sales information after the generic launched, provided "plausible indicia" from which the court could infer that the alleged No-AG commitment represented a large and unjustified transfer of value to the generic. *Id.* at 404; *see also id.* at 405 (observing that a No-AG clause implies that "[o]nce the generic enters . . . it faces no competition . . ."). Also important to the Third Circuit was the fact that Teva sued GSK to enforce the No-AG agreement and thereby prevent GSK from competing with Teva during the 180-day period of generic exclusivity. *Id.* at 397; *see also Teva Pharm. Indus., Ltd., et al. v. SmithKline Beecham Corp.*, No. 08-cv-03706, 2009 WL 1687457, at *1 (D.N.J. June 16, 2009) (noting that Teva sued GSK

to prevent GSK from launching an AG of Lamictal because the parties' patent settlement agreement "made clear that [Teva's] right [to sell generic Lamictal] was exclusive—***including as to GSK and its affiliates***" (emphasis added)).

Thus, in *Lamictal*, the license agreement was available to plaintiffs before they filed their complaint and it could not have been clearer that the exclusivity Teva received—which under the definition in the agreement included an AG—applied to GSK and its affiliates, not just third parties, and that Teva intended the No-AG commitment to protect it from competition from GSK during the 180-day period. *See* Lamictal Settlement Agreement at 4-5, § 2.3(a), attached as Exhibit B (providing Teva with an exclusive license "***including as to GSK and its Affiliates*** and Third Parties with respect to" any generic formulation of Lamictal (emphasis added)).

In *In re Loestrin 24 Fe Antitrust Litigation*—another case on which DPPs rely (Compl. ¶ 84 n. 33)—the complaint contained plausible factual allegations of a large and unexplained reverse payment in the form of an express No-AG arrangement with no carve-outs allowing the brand to compete ***plus*** two favorable side deals between the branded firm and two different ANDA filers. 814 F.3d at 546-47 (describing allegations that the brand manufacturer agreed with the first-filed ANDA holder not to compete during the period of 180-day generic exclusivity and agreed to lucrative promotional and revenue sharing deals on different medications, and that the brand settled with the second-filed ANDA holder and agreed to license a different product as well as a supply arrangement on another medication).

No such facts are present here because Merck did not agree to an express and blanket No-AG clause or to refrain from engaging in price competition with Glenmark. Moreover, Merck's express preservation of its ability to compete in multiple ways runs counter to the primary driver of value in *Lamictal*, which was a promise that the generic would face no "risk of competition"

upon its market entry. 791 F.3d at 394, 405. Given the key distinctions between the terms of the Settlement Agreement here and the facts in *Lamictal* and the other nonbinding decisions in which courts have addressed express No-AG clauses, the cases cited by DPPs in their Complaint actually undercut, rather than support, DPPs' claims. *See* Appendix A[11]; *cf. In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 752, 754 (E.D. Pa. 2015), *aff'd sub nom., In re Wellbutrin Antitrust Litig Indirect Purchaser Clas*s, 868 F.3d 132 (3d Cir. 2017) (affirming dismissal and noting that agreement contained unique features that differentiated the arrangement from other alleged No-AG agreements reviewed by courts to date).

* * *

In sum, given the express and unique terms of the Settlement Agreement, DPPs' Complaint fails to allege "facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment." *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d at 552. Accordingly, DPPs' "antitrust claims fail, and the [c]ourt need not go any further." *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d at 716.

B. DPPs' Section 1 Claim Also Fails Because DPPs Have Not Adequately Alleged Anticompetitive Effects.

DPPs have not plausibly alleged that the Settlement Agreement had anticompetitive effects—as is necessary to state a claim under the rule of reason—because, as the Complaint concedes, a reissued version of the '721 patent was found to be valid and enforceable by the very same judge who presided over the Merck-Glenmark patent litigation. DPPs' allegation that

[11] Appendix A summarizes the types of payment terms alleged in the reverse payment settlement cases DPPs cite in their Complaint. Compl. ¶ 84 n.33. All of those cases involve alleged payment terms that are not present in the Settlement Agreement here, and none of the cases DPPs cite involved allegations that the brand manufacturer expressly preserved its ability to compete with the generic manufacturer. *See* Appendix A.

Glenmark would have won the patent litigation against Merck over the '721 patent, which is essential to their Section 1 claim, is thus implausible on its face.

In the context of an alleged reverse payment, anticompetitive effects are present only if the settlement acts to protect a weak patent that would have been invalidated if the litigation had not been settled by the parties. *Actavis, Inc.*, 570 U.S. at 152 (noting that reverse payments involve a scenario where the plaintiff "pays money to [a] defendant … purely so [the defendant] will give up the patent fight"). Indeed, if the patent at issue is valid, a settlement that allows for entry before patent expiry—like the one DPPs challenge here—would be pro-competitive because it facilitated generic competition earlier than the patent allows. *Id*. at 154 (acknowledging that "settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit").

Recognizing these principles, DPPs contend that absent the alleged reverse payment in the form of the (non-existent) No-AG in the Settlement Agreement, Glenmark would have prevailed at trial, invalidated Merck's '721 patent, and launched as early as December 6, 2011. Compl ¶¶ 201-04. But it is fundamentally implausible to infer that Glenmark would have won its patent litigation against Merck when, as the Complaint concedes, Merck later won a similar patent litigation in which the validity of the reissued version of the '721 patent was upheld. As expressly alleged in DPPs' Complaint, Merck and Mylan litigated the validity of the '461 patent (which was a reissued version of the '721 patent) in a bench trial before the very same district court judge who presided over the Merck-Glenmark litigation. There, the court found that the '461 patent was valid and enforceable. *Id.* ¶¶ 240-241; *Schering Corp., et al. v. Mylan Pharms., Inc.*, No. 09-cv-6383, ECF No. 444, at 1 (D.N.J. Apr. 27, 2012). The Federal Circuit affirmed. Compl. ¶ 241 n.62; *Merck Sharp & Dohme Corp. et al. v. Mylan Pharms. Inc.*, No. 2012-1434,

ECF No. 49-1 (Fed. Cir. Feb. 7, 2013). Moreover, DPPs do not point to a single example where a compound patent had been successfully challenged in the context of Hatch-Waxman litigation when Glenmark and Merck reached the Settlement. Thus, on the face of the Complaint, DPPs' allegation that Glenmark would have won the patent trial giving if it had not entered into the Settlement Agreement in this case—which, of course, is essential to any finding of anticompetitive effects—is facially implausible. *See Dudley v. Focused Recovery Sols., Inc.*, No. 17-cv-10, 2017 WL 2981345, at *6 (E.D. Va. July 12, 2017) (concluding that where "the factual allegations undercut" a plaintiff's claims, "any contrary inference [of improper conduct by the defendant] is unwarranted"). And, in the absence of plausible allegations of anticompetitive effects, DPPs' Section 1 claim under the rule of reason cannot survive.

In an attempt to reckon with these facts, DPPs downplay Merck's win by positing that Mylan elected to pursue the "cheapest and fastest" trial strategy instead of "the best substantive defense." Compl. ¶ 239. It is implausible and defies common sense to suggest that Mylan would have proceeded to trial on anything but its strongest claims, and it lost on those claims. But, even if one were to look beyond the obvious implausibility of this assertion, these allegations are beside the point given the indisputable fact that Merck's patent was litigated to a bench trial on issues that overlapped with Glenmark's claims, and Merck prevailed. There is no well-pled factual basis in the Complaint to support the inference that the suit between Merck and Glenmark would have resulted in a different outcome. Instead, the only plausible inference from Merck's win is that Glenmark would not have been successful in invalidating the '721 patent and that therefore the Settlement was, in fact, procompetitive because it made it possible for Glenmark to compete earlier than it otherwise could have. Because DPPs' Complaint contains no plausible allegations that Glenmark would have prevailed and invalidated Merck's patent, and

inasmuch as the facts alleged give rise to the opposite inference, DPPs have not pled actionable anticompetitive effects.[12] DPPs' Section 1 must be dismissed for this additional reason.

C. The Section 2 Claim Fails for the Same Reasons as the Section 1 Claim and for the Independent Reason that DPPs Have Not Plausibly Alleged Specific Intent.

The Section 2 claim fails because the plain terms of the Settlement Agreement belie DPPs' assertion that Merck and Glenmark conspired for the purposes of agreeing to a No-AG clause. Compounding this dispositive flaw, DPPs have not alleged facts to establish that any one Defendant acted with the specific intent to monopolize, as required for their conspiracy to monopolize claim in Count II. Compl. ¶¶ 324-26. To plead "a claim for conspiracy to monopolize, a plaintiff must show concerted action, a specific intent to achieve an unlawful monopoly, and commission of an overt act in furtherance of the conspiracy." *Advanced Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 150 (4th Cir. 1990). Specific intent is conduct undertaken with the desire "to destroy competition or build a monopoly" that requires a plaintiff to show that the defendant "sought to create a monopoly by circumventing the competitive process." *Abcor Corp. v. AM Int'l, Inc.*, 916 F.2d 924, 927 (4th Cir. 1990). Dismissal is required where a complaint "is devoid of any factual allegations" establishing specific intent. *Int'l Constr. Prod. LLC v. Caterpillar Inc.*, No. 15-cv-108, 2016 WL 264909, at *9 (D. Del. Jan. 21, 2016) (dismissing conspiracy to monopolize claim where there were no facts alleged to establish specific intent); *see also Masco Contractor Servs. E., Inc. v. Beals*, 279 F.

[12] DPPs assert in the alternative that, absent the alleged reverse payment, Glenmark and Merck would have negotiated a "reasonable, economically rational" settlement. Compl. ¶ 200. There are simply no well-pled factual allegations that plausibly suggest that Merck and Glenmark would have reached such a re-imagined compromise, let alone what the terms of such an alternative agreement that DPPs deem "reasonable" would have been. Moreover, *Actavis* "requires only that a brand manufacturer not unlawfully restrict competition; it does not demand that the brand maximize competition." *In re Actos*, 2015 WL 5610752, at *16.

Supp. 2d 699, 708 (E.D. Va. 2003) (dismissing attempt to monopolize claim where "no facts are alleged that support [the] inference" of specific intent).

Here, the Complaint contains no factual allegations of specific intent. For example, DPPs do not allege which entity or entities they believe acted with a specific intent to bestow a monopoly on any one Defendant or why. At most, DPPs allege that the seven various Merck and Glenmark named Defendants conspired to artificially maintain higher prices of Zetia and its generic counterpart longer than would have existed absent the alleged (nonexistent) agreement not to launch an AG. *See* Compl. ¶¶ 85-86. But, as this Court has explained, "discriminatory and deceptive pricing" does not rise to the level of circumstantial evidence of specific intent to monopolize. *Am. Online, Inc. v. GreatDeals.Net*, 49 F. Supp. 2d 851, 860 (E.D. Va. 1999) (dismissing attempted monopolization claim for failure to plead direct or circumstantial facts supporting a plausible inference of specific intent); *see also Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602 (1985) (specific intent means "an intent which goes beyond the mere intent to do the act" (citation omitted)). Accordingly, because the Complaint does not plausibly allege that any one Defendant acted with specific intent to monopolize, the Section 2 claim is missing an essential element and must be dismissed.

V. CONCLUSION

For the foregoing reasons, the Complaint fails to state a claim and should be dismissed in full and with prejudice.

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Respectfully submitted,

/s/ J. Kevin Fee

J. Kevin Fee (Bar No. 88376)
Teri J. Diaz (Bar No. 87457)
MORGAN, LEWIS & BOCKIUS LLP
1111 Pennsylvania Ave., NW
Washington, D.C. 20005
Tel: 202.739.3000
Fax: 202.739.3001
kevin.fee@morganlewis.com
teri.diaz@morganlewis.com

Steven A. Reed (admitted *pro hac vice*)
R. Brendan Fee (admitted *pro hac vice*)
Zachary M. Johns (admitted *pro hac vice*)
Jessica J. Taticchi (admitted *pro hac vice*)
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103
Tel: 215.963.5000
Fax: 215.963.5001
steven.reed@morganlewis.com
brendan.fee@morganlewis.com
zachary.johns@morganlewis.com
jessica.taticchi@morganlewis.com

Stacey Anne Mahoney (admitted *pro hac vice*)
MORGAN, LEWIS & BOCKIUS LLP
101 Park Ave.
New York, NY 10178
Tel: 212.309.6000
Fax: 212.309.6001
stacey.mahoney@morganlewis.com

Counsel for Defendants
Glenmark Pharmaceuticals, Ltd. and
Glenmark Pharmaceuticals Inc., USA incorrectly identified as Glenmark Generics Inc., USA

CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2018, I caused a true and correct copy of the foregoing to be filed on the Court's CM/ECF system which will cause copies of the same to be served upon all counsel of record. I further certify that I caused a true and correct copy of all materials filed under seal to be served on the following local and lead counsel via email and Federal Express:

William H. Monroe, Jr.
GLASSER AND GLASSER, P.L.C.
Crown Center, Suite 600
580 East Main Street
Norfolk, VA 23510
Telephone: (757) 625-6787
Facsimile: (757) 625-5959
bill@glasserlaw.com

Local Counsel and Interim Class Counsel for Direct Purchaser Plaintiffs

Thomas M. Sobol
Kristen A. Johnson
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, MA 02142
Telephone: (617) 482-3700
Facsimile: (617) 482-3003
tom@hbsslaw.com
kristenj@hbsslaw.com

Lead Counsel and Interim Class Counsel for Direct Purchaser Plaintiffs

Alan Brody Rashkind
James A. Cales, III
FURNISS, DAVIS, RASHKIND & SAUNDERS, PC
6160 Kempsville Circle, Suite 341B
Norfolk, Virginia 23502
Telephone: (757) 461-7100
Facsimile: (757) 461-0083
arashkind@furnissdavis.com
jcales@furnissdavis.com

Local Counsel for the Proposed End-Payer Class

Michael M. Buchman
Motley Rice LLC
600 Third Avenue, Suite 2101
New York, NY 10016
Telephone: (212) 577-0040
Facsimile: (212) 577-0050
mbuchman@motleyrice.com

Marvin A. Miller
MILLER LAW LLC
115 South LaSalle Street, Suite 2910
Chicago, Illinois 60603
Telephone: (312) 332-3400
MMiller@millerlawllc.com

Co-Lead and Interim Co-Class Counsel for the Proposed End-Payer Class

Scott E. Perwin
KENNY NACHWALTER PA
1441 Brickell Ave. Suite 1100
Miami, FL 33131
Telephone: (305) 373-1000
Facsimile: (305) 372-1861
sperwin@knpa.com

Lead Counsel for Retailer Plaintiffs

Eric L. Bloom
HANGLEY ARONCHICK SEGAL PUDLIN & SCHILLER
2805 Old Post Road, Suite 100
Harrisburg, PA 17110
Telephone: (717) 364-1030
ebloom@hangley.com

Lead Counsel for Rite Aid and CVS Plaintiffs

Craig C. Reilly
111 Oronoco Street
Alexandria, VA 22314
Telephone: (703) 549-5354
Facsimile: (703) 549-5355
craig.reilly@ccreillylaw.com

Local Counsel for Retailer Plaintiffs

Stephen E. Noona
KAUFMAN & CANDLES, P.C.
150 W. Main Street, Suite 2100
Norfolk, VA 23510-1665
Telephone: (757) 624-3239
Facsimile: (888) 360-9092
senoona@kaufcan.com

Local Counsel for Defendants
Merck & Co., Inc.; Merck Sharp & Dohme Corp.;
Schering-Plough Corp.; Schering Corp. and MSP
Singapore Co. LLC

Samuel G. Liversidge
GIBSON, DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071-3197
Telephone: (213) 229-7855
Facsimile: (213) 229-6855
SLiversidge@gibsondunn.com

Tarek Ismail
Jennifer L. Greenblatt
GOLDMAN ISMAIL TOMASELLI
BRENNAN & BAUM LLP
564 West Randolph Street, Suite 400
Chicago, IL 60661
Telephone: (312) 681-6000
Facsimile: (312) 881-5191
tismail@goldmanismail.com
jgreenblatt@goldmanismail.com

Lead Counsel for Defendants
Merck & Co., Inc.; Merck Sharp & Dohme Corp.;
Schering-Plough Corp.; Schering Corp. and MSP
Singapore Co. LLC

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/s/ Zachary M. Johns
Zachary M. Johns

Counsel for Defendants
Glenmark Pharmaceuticals, Ltd. and Glenmark
Pharmaceuticals, Inc. USA incorrectly identified as
Glenmark Generics Inc., USA